Pernix Therapeutics Inc. Obtains Six Months U.S. Pediatric Exclusivity for Treximet

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MORRISTOWN, NJ – (BUSINESS WIRE) – April 20, 2015 – Pernix Therapeutics Holdings, Inc. (NASDAQ: PTX), a specialty pharmaceutical company, today announced that Pediatric Exclusivity has been granted by the U.S Food and Drug Administration (FDA) for studies conducted on Treximet® (sumatriptan/naproxen sodium), effective April 16, 2015, under section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a). Based on this decision, an additional six months of U.S. market exclusivity will attach to the patents that are listed in FDA's Orange Book for Treximet, or until February 14, 2018.

"We are pleased to have received Pediatric Exclusivity for Treximet and look forward to receiving FDA approval, later this year, for the use of Treximet in adolescent patients who suffer from the debilitating effects of migraine pain. The designation allows us to extend the Treximet's lifecycle and places us one step closer to extending the benefits of the product to the underserved adolescent population," said Douglas Drysdale, Chairman, President and Chief Executive Officer of Pernix Therapeutics.

The approval of pediatric exclusivity does not mean that Treximet is approved for use in pediatric patients. Treximet is FDA-approved only for use in adults aged 18 and older. As previously reported, on November 14, 2014, Pernix submitted a sNDA seeking approval for Treximet for use in adolescent patients, age 12 – 17, for the acute treatment of migraine, with or without aura. Included in the filing are safety and efficacy data sets from three trials conducted to evaluate the pharmacokinetic, efficacy, and long-term safety of Treximet for the acute treatment of adolescent migraine. The Company expects approval for Treximet in adolescent patients in the second quarter of 2015, based on the anticipated Prescription Drug User Fee Act (PDUFA) action date.

Migraine has an estimated prevalence of 8% to 23% in children ≥ 11 years of age.[1] Treatments, both acute and prophylactic, are similar to those used in adults.[2,3] Sumatriptan is the most widely studied triptan in adolescents.[6,7] However, studies of sumatriptan alone failed to demonstrate efficacy versus placebo for the primary end points, chiefly due to high placebo response.[7-13] In adults, TREXIMET, the combination of sumatriptan and naproxen sodium, has demonstrated superior efficacy, similar tolerability, and improved quality of life and medication satisfaction to its components.[14-17]

About TREXIMET

TREXIMET was first approved by the U.S. Food and Drug Administration (FDA) in April 2008 for the acute treatment of migraine attacks, with or without aura, in adults. The product is formulated with POZEN's patented technology of combining a triptan with a non-steroidal anti-inflammatory drug (NSAID) and GlaxoSmithKline's (GSK) RT Technology™. TREXIMET has been shown to provide superior sustained pain relief compared to placebo and to both of the single mechanism of action components. In clinical trials, TREXIMET provided a significantly greater percentage of patients with migraine pain relief at two hours compared to sumatriptan 85 mg or naproxen sodium 500 mg alone. In addition, TREXIMET provided more patients sustained migraine pain relief from two to 24 hours compared to the individual components.

IMPORTANT SAFETY INFORMATION

Prescription TREXIMET is indicated for the acute treatment of migraine attacks, with or without aura, in adults. Carefully consider the potential benefits and risks of TREXIMET and other treatment options when deciding to use TREXIMET. TREXIMET is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine (see CONTRAINDICATIONS). Safety and effectiveness of TREXIMET have not been established for cluster headache. TREXIMET should only be used where a clear diagnosis of migraine headache has been established. TREXIMET may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction,

and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk. TREXIMET contains a non-steroidal anti-inflammatory drug (NSAID). NSAID-containing products cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events. TREXIMET is contraindicated in patients with history, symptoms, or signs of ischemic cardiac, cerebrovascular, or peripheral vascular syndromes and in patients with other significant underlying cardiovascular diseases. TREXIMET should not be given to patients in whom unrecognized coronary artery disease is predicted by the presence of risk factors without a prior cardiovascular evaluation. TREXIMET should not be given to patients with uncontrolled hypertension because the components have been shown to increase blood pressure. Concurrent administration of MAO-A inhibitors or use of TREXIMET within two weeks of discontinuation of MAO-A inhibitor therapy is contraindicated. TREXIMET and any ergotamine-containing or ergot-type medication (like dihydroergotamine and mthysergide) should not be used within 24 hours of each other. Since TREXIMET contains sumatriptan, it should not be administered with another 5-HT1 agonist.

TREXIMET is contraindicated in patients with hepatic impairment. TREXIMET is contraindicated in patients who have had allergic reactions to products containing naproxen. It is also contraindicated in patients in whom aspirin or other NSAIDs/analgesic drugs induce the syndrome of asthma, rhinitis, and nasal polyps. Both types of reactions have the potential of being fatal. TREXIMET is contraindicated in patients with hypersensitivity to sumatriptan, naproxen, or any other component of the product. Cerebrovascular events have been reported in patients treated with sumatriptan. In a number of cases, it appears possible that the cerebrovascular events were primary. It is important to advise patients not to administer TREXIMET if a headache being experienced is atypical. The development of a potentially life-threatening serotonin syndrome may occur with triptans, including treatment with TREXIMET, particularly during combined use with selective serotonin reuptake inhibitors (SSRIs) or selective norepinephrine reuptake inhibitors (SNRIs). NSAID-containing products, including TREXIMET, should be prescribed with extreme caution in those with a prior history of ulcer disease or gastrointestinal bleeding. TREXIMET should not be used in late pregnancy because NSAID-containing products have been shown to cause premature closure of the ductus arteriosus. TREXIMET should not be used during early pregnancy unless the potential benefit justifies the potential risk to the fetus.

About Pernix Therapeutics

Pernix Therapeutics is a specialty pharmaceutical business with a focus on acquiring, developing and commercializing prescription drugs primarily for the U.S. market. The Company targets underserved therapeutic areas such as CNS, including neurology and psychiatry, and has an interest in expanding into additional specialty segments. .

To learn more about Pernix Therapeutics, visit www.pernixtx.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Statements including words such as "estimate," "plan," "project," "forecast," "intend," "expect," "anticipate," "believe," "seek," "target" or similar expressions are forward-looking statements. Because these statements reflect the Company's current views, expectations and beliefs concerning future events, these forward-looking statements involve risks and uncertainties. Investors should note that many factors, as more fully described under the caption "Risk Factors" in our Form 10-K, Form 10-Q and Form 8-K filings with the Securities and Exchange Commission and as otherwise enumerated herein or therein, could affect the Company's future financial results and could cause actual results to differ materially from those expressed in forward-looking statements contained in the Company's Annual Report on Form 10-K. The forward-looking statements in this press release are qualified by these risk factors. These are factors that, individually or in the aggregate, could cause our actual results to differ materially from expected and historical results. The Company assumes no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

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